

Remarks

Applicant appreciates the thorough examination of the present application as evidenced by the final Office Action dated August 2, 2004 (hereinafter, the "Final Action").

Claims 22-24, 31, 32, 37, 44, 49 and 51-53 are pending in the present application. Claims 22-24, 31, 32, 37, 44, 49 and 51-53 stand rejected. Applicant respectfully submits the current Amendment After Final to expedite allowance of claims that appear to be indicated in the Final Action as containing allowable subject matter as further discussed below.

I. Allowable Subject Matter

The Final Action states the following:

Based on the unexpected benefit presented in the declaration, the following subject matter would be allowable:

A method of administering a sodium channel blocker to an airway surface of a subject in need thereof, comprising administering the sodium channel blocker in an effective therapeutic amount in a vehicle, said vehicle comprising potassium sulfate as an ionic osmolyte, said potassium sulfate included in an amount effective to increase the volume of liquid on the airway surface, wherein said subject is afflicted with cystic fibrosis.

Final Action, page 5.

Applicant has amended the claims along the lines as suggested above. More specifically, the recitations of Claim 52 have been incorporated into Claim 51. Applicant has included, however, a recitation directed to the vehicle comprising "potassium sulfate or **potassium phosphate**." Applicant notes that the Declaration of Dr. Richard C. Boucher, Jr. Under 37 C.F.R. § 1.132 provided unexpected results that show an increase in drug penetration associated with the methods of the present invention. In particular, figure 2 illustrated a response wherein a hypertonic solution containing ~300 mM **potassium phosphate** was added to the apical surface rather than isotonic saline. As provided in the Declaration of Dr. Boucher, the hypertonic solution containing **potassium phosphate** swelled the mucus, allowing the drug surrogate (fluorescein) to penetrate to the cell surface, following which there was rapid cellular uptake of the surrogate. Thus, Applicant respectfully submits that amended Claim 51 is allowable.

Applicant has also added new Claims 54-56. Support for these new claims can be found in the claims as well as the specification, for example, page 5, lines 20-28 and page 11, lines 25-27, among other places.

In re: Boucher, Jr.
Serial No.: 09/465,429
Filed: December 21, 1999
Page 4 of 4

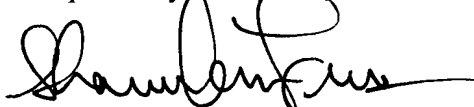
Accordingly, Applicant respectfully submits that no new matter is added by the entry of these claim amendments and new claims, and respectfully request entry and allowance thereof.

II. Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

It is not believed that any fee(s), including fees for additional claims, are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that additional fees are necessary to allow consideration of this paper, such an extension is also hereby petitioned for under 37 C.F.R. §1.136(a). Applicants authorize that any additional fees believed to be due in connection with this paper may be charged to Deposit Account No. 50-0220.

Respectfully submitted,



Shawna Cannon Lemon
Registration No. 53,888

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec, P.A.
P. O. Box 37428
Raleigh, North Carolina 27627
Telephone: (919) 854-1400
Facsimile: (919) 854-1401

CERTIFICATE OF EXPRESS MAILING

Express Mail Label No. EV 473665081
Date of Deposit: November 18, 2004

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Susan E. Freedman
Date of Signature: November 18, 2004